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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,327	12/01/2003	Nathan Andrew Shapira	UF-343X	3664

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EXAMINER

WEDDINGTON, KEVIN E

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 03/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/726,327

Applicant(s)

SHAPIRA ET AL.

Examiner

Kevin E. Weddington

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 01 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5-20-04</u> . | 6) <input type="checkbox"/> Other: _____ |

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Claims 1-7 are presented for examination.

Applicants' drawing filed December 1, 2003 and the information disclosure statement filed May 20, 2004 have been received and entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating or controlling or reducing swelling or inflammation associated with lipoma with the administering of topiramate, does not reasonably provide enablement for treating all types of diseases, disorder, tumors, cancers and neoplasia. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per factors indicated in the decision In re Wands, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation.

The factors include:

- 1) the quantity of experimentation necessary
- 2) the amount of direction or guidance provided
- 3) the presence or absence of working examples
- 4) the nature of the invention

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- 5) the state of the art
- 6) the relative skill of those in the art
- 7) the predictability of the art and
- 8) the breadth of the claims

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice that instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The claimed invention relates to a method for treating or controlling or reducing swelling or inflammation associated with a disease, disorder, benign tumor, malignant tumor, malignant cancer, or malignant neoplasia in an individual comprising the administration of an effective amount of a composition comprising an anti-convulsant and a pharmaceutically acceptable carrier to said individual, wherein said effective amount is sufficient to reduce or eliminate the disease or disorder associated swelling.

The Cecil Textbook of Medicine, 21st Edition, shows that for the various known cancer types there is no one specific chemotherapeutic agent that is effective for all types of cancer (See Table 198-5 at page 1065; table 198-6 at page 1066; table 198-8 at page 1068; and table 198-9 at page 1071).

The relative skill of those in the art is generally that of a Ph.D. or M.D.

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The present invention is unpredictable unless experimentation is shown that anti-convulsant agents can treat all types of tumors, cancers, neoplasia, diseases and disorders.

The breadth of the claims

The claims are very broad and inclusive to all types of tumors, cancers, neoplasia, diseases and disorders.

The amount of direction or guidance provided and the presence or absence of working examples

The working example I is limited to the administration of topiramate to treat lipoma in a German Shorthaired Pointer (dog).

No examples showing any anticonvulsant agents are effective in treating or controlling or reducing swelling or inflammation associated with all types of tumors, cancers, neoplasia, diseases and disorders.

The quantity of experimentation necessary

Applicants have failed to provide guidance as to how anti-convulsants are effective in treating or controlling or reducing swelling or inflammation associated with all types of tumors, cancers, neoplasia, diseases and disorders. Therefore, undue experimentation would be required to practice the invention as it is claimed in its current scope.

Claims 1-7 are not allowed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Mary Relling et al., "Adverse effect of anticonvulsants on efficacy of chemotherapy for acute lymphoblastic leukaemia", The Lancet, Vol. 356, pp. 285-290 (July 2000) of PTO-1449.

Relling et al. teach the use of anticonvulsants in the treating of acute lymphoblastic leukaemia (a type of cancer). Note under the section, Introduction, second paragraph, teaches the anticonvulsants were combined with various additional therapeutic agents such as vinca alkaloids. Clearly, the cited reference teaches anticonvulsants are well-known to treat acute lymphoblastic leukaemia (cancer) and can be combined with additional therapeutic agents. Therefore, the applicants' instant invention is unpatentable by the anticipation of the cited reference.

Claims 1-5 are not allowed.

Claims 1-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Ikonomidou (6,797,692 B1).

Ikonomidou teaches a method for treating cancer by administering an inhibitor of the interaction of glutamate with the AMPA receptor complex. Note in column 13, claim 4, one of the inhibitors is topiramate, applicants' preferred anticonvulsant. Clearly, the reference teaches topiramate can treat cancer. Also note in column 14,

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claim 7, the inhibitor can be combine with various additional agents such as an alkylating agent or vinca alkaloids or platinum coordination complexes. Again, the cited reference anticipates the applicants' instant invention.

Claims 1-6 are not allowed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ikonomidou (6,797,692 B1) in view of Costenzo et al. (5,498,629), Choi et al. (5,654,461) and Choi et al. (5,892,008).

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Ikonomidou was discussed above supra for the use of topiramate to treat cancer and the addition of other compounds used to treat cancer combined into a single composition.

The instant invention differs from the cited reference in that the cited reference does not teach the other anticonvulsants disclosed in claim 7 can be used in the composition. However, the secondary references, Costenzo et al., Choi et al., and Choi et al., teaches the fructopyranose sulfamates compounds are derivatives of topiramate. Therefore, one skilled in the art would assumed the fructopyranose sulfamate compounds possess the same anticancer activities, thus the substitution of topiramate with the fructopyranose sulfamate compounds would achieve the same anticancer results in the absence of evidence to the contrary.

Claims 1-7 are not allowed.

The remaining references listed on the enclosed PTO-892 are cited to show the state of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571)272-0587. The examiner can normally be reached on 11:00 am-7:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Kevin E. Weddington
Primary Examiner
Art Unit 1614

K. Weddington
March 3, 2006